

European Union Reference Laboratory for Rabies

WORK PROGRAMME 2012

I. Legal duties

The functions and duties of the European Union Reference laboratory (EURL) for rabies are described in the Commission Regulation (EC) No 737/2008 designating the EURL for crustacean diseases, rabies and bovine tuberculosis, laying down additional responsibilities and tasks for the EURL for rabies and bovine tuberculosis and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council.

II. Objectives for the period January - December 2012

1 Technical support: producing, storing and supplying biological materials and virus collection (multi-annual)

The biological materials that will be available for rabies diagnosis and typing are

- Polyclonal conjugates (1 vial per laboratory);
- Positive controls infected with genotypes 1, 4, 5, 6, 7 (available in the laboratory and subject to the consent of the owner of the strain) and negative controls for rabies diagnosis and for typing;
- Lyophilised preparations of fixed reference viruses (CVS 11 for *in vitro* tests and CVS 27 for *in vivo* tests).

The biological materials that will be available for bait titration and other applications are

- Virus SAG2, VRG, SAD B19 and SAD Bern, if authorisation to produce the viruses has been received.

The biological materials and facilities that will be available for follow-up of oral vaccination campaigns include the following:

- CD-ROM describing the operating procedure for determining tetracycline uptake;
- an EURL experimental station with foxes and raccoon dogs;

- Fox teeth samples (positive and negative controls for determining tetracycline uptake).

2 Technical support: confirmatory tests

2.1 Support for diagnosis (*multi-annual*)

The EURL will receive, examine and report on samples submitted by EU Member States.

2.2 Support for typing (*multi-annual*)

The EURL will type strains from NRLs upon request. FTA® paper will be offered to NRLs to simplify and reduce the cost of shipping samples.

2.3 Support for bait titration (*multi-annual*)

Bait titration before implementation of an oral vaccination programme can be performed by EURL at the request of NRLs.

3 Inter-laboratory tests

3.1 Inter-laboratory test to evaluate Tetracycline and Age determination on red fox tooth

The technique of tetracycline and age determination is widely used within Europe in the frame of oral vaccination follow-up. Most of baits include tetracycline to provide a life-long marking of bones and teeth of the bait consumers. When applying oral rabies vaccination, international institutions (WHO, OIE, EC) recommend to control the vaccination effectiveness by notably analysing the presence of fluorescence in teeth. A second inter-laboratory test, following the one of 2010, will be conducted on this technique.

- Contacting all European National Reference Laboratories (and possibly those from third countries) to establish a list of interested laboratories;
- collecting positive and negative reference materials;
- Distributing a panel of characterised samples for inter-laboratory comparison and validation;

Remark: Such inter-laboratory test needs transport in dry ice to ensure stability of the samples.

- Interpreting all results of participating laboratories, then writing and publishing a synthesis report.

On the basis of the inter-laboratory test results (3.1) and the synthesis of procedures used in Member States (4.1), a guide describing the main important points to consider in each step of the tetracycline and age determination procedure will be elaborated. The objective of this guide is to obtain, if possible, the standardisation of this method within Europe.

3.2 Inter-laboratory test to evaluate recommended rabies diagnostic tests (*annual*)

The fluorescent antibody test (FAT), rabies tissue culture inoculation test (RTCIT) and mouse inoculation test (MIT) are the gold standard tests for rabies diagnosis. An inter-laboratory test will be conducted by:

- Contacting all European laboratories (and possibly those from third countries) to establish a list of interested laboratories;
- Producing positive and negative reference materials;
- Distributing a panel of characterised samples for inter-laboratory comparison and validation;

Remark: Such inter-laboratory test needs transport in dry ice to ensure stability of the samples.

- Interpreting all results of participating laboratories, then writing and publishing a synthesis report.

4 Collecting and collating data on methods used through European Union and standardisation

4.1 Collecting data and information on the methods of Tetracycline and Age determination used by laboratories (annual)

The procedures used within EU Member States for Tetracycline and Age determination on red fox tooth will be collected via questionnaires on techniques. Each step of the protocols will be analysed for all laboratories. A report will be established with a synthesis for all procedures; special attention will be given to technical points that are different or adapted from the existing reference tests.

4.2 Collecting data and information on the methods of rabies diagnosis used by laboratories (FAT; RTCIT; MIT) (annual)

The procedures used within Member States for rabies diagnosis using recommended tests (FAT, RTCIT, MIT) will be collected via questionnaires on the techniques employed. Each step of the protocols will be analysed for all laboratories and compared to the OIE or/and WHO reference tests. A report will be written up with a synthesis for all procedures; special attention will be given to technical points that are different or adapted from the existing and standardised reference tests.

4.3 Collecting data on tests carried out in the EC (annual)

The EURL will request an annual report from each NRL. This will help to evaluate the number of tests performed in EU Member States for diagnosis, typing, bait titration and control of the effectiveness of oral vaccination (tetracycline detection, age determination and serology).

5 Maintaining and enlarging the rabies strain database (multi-annual)

Through the “Rabies database project” working group, the EURL will maintain and enlarge the genomic database of rabies strains isolated within the European Union. The objective is to overcome the lack of epidemiological information regarding rabies strains referenced in the main public sequence databases.

6 Keeping abreast of development in surveillance, epidemiology and prevention of rabies throughout the world (multi-annual)

The EURL will attend and participate in meetings, workshops and conferences in epidemiology and virology in regards to rabies. The EURL will peruse all relevant literature.

7 Research Programme (multi-annual)

The EURL will work in collaboration with several NRLs on rabies epidemiology and evolution of rabies phylogeny.

8 Maintaining and reinforcing the Rabies NRL network

8.1 Organising an annual meeting for NRLs (annual)

This meeting will be organised in 2012 with the objective of sharing information on the work that has been carried out during the year and the different issues that have been addressed. A day training for tetracycline detection and age determination will follow the annual meeting (meeting and training will be performed on two consecutive days for economical reasons; this will allow to reduce travel expenditures of NRLs).

8.2 Providing training to laboratories and possibly visiting them (*multi-annual*)

Upon NRL requests, the EURL will organise on-site training sessions on

- rabies diagnosis,
- typing,
- bait titration and
- biomarker determination.

8.3 Providing scientific advice to the European Commission (*multi-annual*)

The EURL will prepare and submit to the European Commission all technical and scientific reports produced during the year and provide the European Commission with scientific advice and technical assistance.

8.4 Internet website (*multi-annual*)

A website presenting the EURL's aptitudes and activities, a list of the NRLs, news of the laboratory network and agenda of EURL activities will be updated regularly.